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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,948	07/11/2001	Rifat Pamukcu	P-166-1	9861

7590 07/07/2003

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EXAMINER	
HUFF, SHEELA JITENDRA	
ART UNIT	**PAPER NUMBER**
1642	8

DATE MAILED: 07/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/902,948	PAMUKCU ET AL.	
	Examin r	Art Unit	
	Sheela J Huff	1642	

-- The MAILING DATE f this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *8-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: . .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-7 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that a search of the art will result in a search of all the claimed inventions. This is not found persuasive because the different groups require different searches. Additionally applicant requested clarification for Group IV. There is no mention of Group IV in the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

Claims 4-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to identifying neoplasias by determine level of cGMP-specific PDEs in a sample and the elevated level of cGMP-PDEs in neoplasitc relative to normal tissue indicates neoplasia. The state of the art contradicts this. Curtis-Prior et al (Lancet December 4 1976) indicates enzymes activities are 3-5 times greater in **normal tissue** than cancer tissue (see p. 1224, first col. last full paragraph). Since applicant has provided no examples to that the increase in levels of cGMP-PDEs is in neoplastic tissue and since the state of the art contradicts applicant's assertion, undue

experimentation would be required by one skilled in the art to determine if the levels were elevated or not.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 are directed to an invention not patentably distinct from claims 1-2 and 4 of commonly assigned US Patent 6130053. Specifically, the only difference between the two sets of claims is that the claims of the patent also include the set of determining protein kinase G activity. Since the method claims in the instant application "comprise" contacting a cGMP-PDE inhibitory compound with neoplasia and since "comprising" is open language the claims read on each other. Even though the claims in the patent are selecting a compound and the claims of the instant application are identifying neoplasia, the process of the two methods overlap in that both sets of claims involve contacting a cGMP-PDE inhibitory compound with neoplasia. Because both

sets of claims have the same set, it is expected that if one of skill in the art is selecting for a compound for the treatment for neoplasia, that one is at the same time identifying the neoplasia that compound can treat.

Claims 1-3 are directed to an invention not patentably distinct from claim 14 of commonly assigned US Patent 6156528 or from claim 26 of US Patent 5858694. Specifically, the only difference between the two sets of claims is that the claims of the patent also includes a selecting step. Even though the claims in the patent are selecting a compound and the claims of the instant application are identifying neoplasia, the process of the two methods overlap in that both sets of claims involve contacting a cGMP-PDE inhibitory compound with neoplasia. Because both sets of claims have the same set, it is expected that if one of skill in the art is selecting for a compound for the treatment for neoplasia, that one is at the same time identifying the neoplasia that compound can treat.

Commonly assigned US Patent 6130053 and US Patent 6156528 and US Patent 5858694, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter.

Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g).

Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 and 4 of U.S. Patent No. 6130053. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the two sets of claims is that the claims of the patent also include the set of determining protein kinase G activity. Since the method claims in the instant application "comprise" contacting a cGMP-PDE inhibitory compound with neoplasia and since "comprising" is open language the claims read on each other. Even though the claims in the patent are selecting a compound and the claims of the instant application are identifying neoplasia, the process of the two methods overlap in that both sets of claims involve contacting a cGMP-PDE inhibitory compound with neoplasia. Because both sets of claims have the same set, it is expected that if one of skill in the art is selecting for a compound for the treatment for neoplasia, that one is at the same time identifying the neoplasia that compound can treat.

Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 14 of U.S. Patent No. 6156528 or

over claim 26 of US Patent 5858694. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the two sets of claims is that the claims of the patent also includes a selecting step. Even though the claims in the patent are selecting a compound and the claims of the instant application are identifying neoplasia, the process of the two methods overlap in that both sets of claims involve contacting a cGMP-PDE inhibitory compound with neoplasia. Because both sets of claims have the same set, it is expected that if one of skill in the art is selecting for a compound for the treatment for neoplasia, that one is at the same time identifying the neoplasia that compound can treat.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Piazza et al, Cancer Res. vol. 55 p. 3110 (1995) or Pamukcu et al US 5401774 as evidenced by Silvola et al Agents and Actions vol. 12 p. 516 (1982).

Piazza et al shows that sulindac sulfide and sulfone (both of which are NSAIDs) inhibit cell growth by inducing apoptosis (see title). The reference is contacting the drug with proliferative activity and show inhibition of said activity. Since the reaction step in the claimed method is the contacting step and determining if the compound inhibits neoplasia, and since the reference is doing both reaction steps, the reference is also inherently identifying neoplasias that can be inhibited by cGMP-PDE. Silvola et al is evidenced to show that it is well known in the art that NSAIDs are potent inhibitors of cGMP-PDE--see page 518, first paragraph in the first column.

Pamukcu et al shows that NSAIDs inhibit the growth of various cell lines (see Example 20 on col. 22). The reference is contacting the drug with proliferative activity and show inhibition of said activity. Since the reaction step in the claimed method is the contacting step and determining if the compound inhibits neoplasia, and since the reference is doing both reaction steps, the reference is also inherently identifying neoplasias that can be inhibited by cGMP-PDE. Silvola et al is evidenced to show that it is well known in the art that NSAIDs are potent inhibitors of cGMP-PDE--see page 518, first paragraph in the first column.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/32379.

This reference discloses that cGMP-PDE inhibits SMC proliferation (see page 44).

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Piazza et al US 5858694 (filed 5/30/97).

This reference discloses a method for identifying a compound with potential for treating neoplasia comprising contacting the compound that has PDE5 inhibiting activity with neoplastic cells and determining that the compound has anti-neoplastic activity (see claim 26 of patent). Even though the claims in the patent are selecting a compound and the claims of the instant application are identifying neoplasia, the process of the two methods overlap in that both sets of claims involve contacting a cGMP-PDE inhibitory compound with neoplasia. Because both sets of claims have the same set, it is expected that if one of skill in the art is selecting for a compound for the treatment for neoplasia, that one is at the same time identifying the neoplasia that compound can treat.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 703-305-7866. The examiner can normally be reached on Tuesday 5:30am-11:30am and Fridays 6:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Sheela J Huff
Primary Examiner
Art Unit 1642

sjh
July 1, 2003